



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY  
AND POLLUTION  
PREVENTION

March 20, 2014

**MEMORANDUM**

**SUBJECT:** Efficacy Review for Rug Doctor;  
EPA Reg. No. 49158-R;  
DP Barcode: D416524

**FROM:** Karen M. Hill, Ph.D.  
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**THRU:** Mark Perry  
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**TO:** Marshall Swindell RM33/ Zebora Johnson  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

**APPLICANT:** Rug Doctor, Inc.  
4701 Old Shepard Place  
Plano, TX. 75093

*K. Hill*  
*3/20/14*

*MJP*

**Formulation from the Label:**

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Hydrogen Peroxide.....	4.85%
Inert Ingredients.....	95.15%
Total.....	100.00%

## **I. BACKGROUND:**

The applicant is seeking to register the product Rug Doctor Antibacterial Carpet Cleaner (EPA Reg. No. 49158-R) as a Carpet and Soft Surface sanitizer for institutional and residential use. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA dated October 29, 2013, EPA Form 8570-4 (CSF), four studies (MRID 492331-12 thru 492331-15), and Statement of No Data Confidentiality Claims for each study.

## **II. USE DIRECTIONS:**

The product is designed for soft surfaces which include uses with back packs, curtains, cushions, kitchen mats, slippers, door mats, diaper bags, box springs, mattresses, gym bags, hampers, pillows, window treatments, sofas, shower curtains, fabrics, comforters, carpets, (canvas)(shoes)(sneakers), desk chairs, covers, (upholstered) couches, (cotton) purses, laundry bags, stuffed animals, upholstery, pet areas, duvet covers, (pet)(dog)(cat)(beds)(bedding), athletic equipment, shoe interior, sheets, (children's) soft fabric toys, (upholstered) car seats, blankets, bedspreads, draperies, entry mats, entry rugs, sleeping bags, (carpeted) stairs, soft (household) surfaces, and bedding.

Directions on the proposed label provide the following information regarding use of the product on carpet:

### **To (one step) clean and sanitize:**

Remove any excess solids, liquid, or dirt. Turn nozzle to spray position. Hold the spray bottle approximately 3 inches from the surface of the carpeting and spray a light even coating on soiled area. Scrub surface with moderate pressure for 30 seconds. Allow to remain wet for (60 minutes) (1 hour) (an hour). Gently blot area with a clean, damp, color-safe cloth. (Repeat as needed (for stubborn stains).) (Let air dry.) (Vacuum.) (Deep clean following your machine's guide.)

### **To preclean (pretreat) (& sanitize):**

Turn nozzle to spray position, hold spray bottle approximately 3 inches from surface and spray a light even coating over soiled area (until damp). Scrub surface with moderate pressure for 30 seconds. Allow to remain wet for 60 minutes (1 hour) (an hour). (Deep clean following your machine's guide).

Directions on the proposed label provide the following information regarding use of the product on surfaces other than carpet:

### **To (one step) clean and sanitize:**

Remove any excess solids, liquid, or dirt. Turn nozzle to spray position. Hold the spray bottle approximately 3 inches from the surface of the carpeting and spray a light even coating on soiled area (fabric) (until damp). Allow to remain wet for 5 minutes. Gently blot area with a clean, damp, color-safe cloth. (Repeat as needed (for stubborn stains or heavy fabrics).) (Let air dry.) (Vacuum.)

**To preclean (pretreat) (& sanitize):**

Turn nozzle to spray position, hold spray bottle approximately 3 inches from surface and spray a light even coating over soiled area (until damp). Allow to remain wet for 5 minutes. (Deep clean following your machine's guide).

**III. AGENCY STANDARDS FOR PROPOSED CLAIMS:**

Spot Soft Surface Sanitization:

The study is designed to evaluate the antimicrobial efficacy of spray application sanitizers on pre-cleaned or lightly soiled, non-food contact soft surfaces. For sanitizer products intended for use on soft, non-food contact surfaces, a fabric carrier method is used to generate efficacy data. The test system proposed is a modification of the ASTM approved method for the evaluation of the antimicrobial efficacy of sanitizers on non-food contact surfaces. The method is modified for spray product application. The Agency recommends the use of The American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (ASTM E1153-03). Three product samples, representing three different batches, one of which should be at least 60 days old, should be tested against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048). The ASTM method states "an average of at least  $7.5 \times 10^5$  organisms must have survived the inoculated control squares for the test to be valid." Two different fabric types should be tested. The fabrics should represent natural fabrics, such as cotton, and synthetic fabrics, such as polyester or rayon. A film of bacterial cells, dried on fabric carriers, is exposed to the test substance for a specified contact time. After exposure, the carriers are transferred to vessel containing neutralizing subculture media and assayed for survivors. Appropriate viability and sterility of organism population and neutralization controls are performed. Carrier type claimed on the label must be consistent with the test system. The test material meets effectiveness requirements of kill an average of at least 99.9% (3 log reduction) of the required organism on the 5 replicate carriers within 5 minutes. Controls must always meet the stipulated criteria.

Carpet Sanitization:

Products bearing label claims for effectiveness as sanitizers for pre-cleaned carpeting must be tested by a protocol incorporating the basic elements of the attached recommended method. If the product is intended to be represented in labeling as a "one-step" cleaner-sanitizer, the method must be modified by including an appropriate soil with the bacterial inoculum. Three product samples representing 3 separate batches, one of which is at least 60 days old, must be tested against *Staphylococcus aureus* ATCC 6538 and *Enterobacter aerogenes* ATCC 13048 with 2 different types of representative synthetic carpeting, such as acrylic and polypropylene tufted-loop types. If the application is intended for hospitals or medical institutions, the product must also be tested against *Pseudomonas aeruginosa* ATCC 15442. If the product is also intended for use on wool carpeting, an additional representative sample of wool carpet must be tested; otherwise, the label must bear a disclaimer for use on wool. All carpet samples tested must be fully identified by the pile fiber type, pile yarn weight of finished carpet, pile density, and tuft height. Adequate controls must demonstrate that bacteriostatic agents in the carpet pile or backing do not yield false-negative data which interfere with the test results. The amount of solution applied to the sample carpeting in the tests must be determined and extrapolated to obtain the amount of the solution of product to be

applied to carpeting (volume per unit area) as stated on the label. A 99.9% reduction of test bacteria over the scrubbed control count must be demonstrated.

Supplemental Claims:

An antimicrobial agent identified as a “one-step” disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

**IV. COMMENTS ON THE SUBMITTED EFFICACY STUDY:**

**A Certificate of Analysis for each batch tested was submitted. The concentration of the active ingredient in each batch is given in the table below:**

Lot	Active Ingredient Concentration
AB06-103112	4.27%
AB08-122712	4.25%
AB12-060713	4.38%
AB11-030712/B	4.20%

**All batches tested were at or below the products LCL of 4.38%.**

**1. MRID # 492331-13. “Carpet Sanitizer,” Test Organism: *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538), for product Rug Doctor Antibacterial Carpet Sanitizer, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – October 22, 2013. Project Identification Number A14808.**

The study was conducted against *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538). Two lots, Lot No. AB06-103112 (≥60 days aged) and Lot No. AB08-122712, of the product Rug Doctor Antibacterial Carpet Sanitizer were tested using ATS Labs protocol No. RUG010172712.CSAN (copy provided). The provided protocol was approved for Rug Doctor, Inc. by EPA in December 2012 under EPA protocol identifier 49158PA1. The product was received as a ready to use trigger spray. A culture of the challenge microorganism was prepared by daily transfers of the organism on Nutrient A slants for ≥3 but ≤30 transfers. The final growth was washed from a 24 ± 2 hours Nutrient A slant using 5.0 mL of phosphate buffer dilution water (PBDW), aspirated, and added to 99.0 mL PBDW. A 2.0 mL aliquot of the inoculum suspension was then added to sufficient Nutrient Agar B bottles and incubated with agar side down for 18 – 24 hours at 25 – 30°C for *Enterobacter aerogenes* and 35 – 37°C for *Staphylococcus aureus*. Following incubation, a 3.0 mL aliquot of PBDW and approximately 15 – 20 sterile glass beads were added to each bottle to suspend the growth. The growth suspension was removed and filtered through sterile gauze pre-wetted with 1.0 mL of PBDW to ensure that any agar harvested with the organism was removed from the test suspension. A 0.20 mL aliquot of Fetal Bovine Serum was added to 3.80 mL of each broth culture to yield a 5% organic soil load. The carriers, sterilized square cut (2 inch X 2 inch) polyester and nylon carpet, were inoculated with 100 µL of the prepared test culture and spread over the upper surface of the carpet using a sterile loop. The inoculated carpet was dried in an incubator at 35 – 37°C with 50.9 – 52.8%

relative humidity for 60 minutes with sterile foil loosely covering the carpet. For testing performed on April 3, 2013, the nylon carriers inoculated with *Enterobacter aerogenes* were dried for 58 minutes. Each carrier was sprayed with the test substance for 10 sprays at a distance of 3 inches. Each carpet carrier was then scrubbed for 30 seconds using 30 circular counterclockwise strokes around a circular area of pile approximately 3 inches (7.6 cm) in diameter around the center of each carrier using a surgical hand brush (4 ¼ X 1 5/8 inch) with ½ inch bristles. For each carpet square, a new sterile brush was used. The treated and scrubbed carpet remained at 21°C with 16% relative humidity on April 3, 2013 and 53% relative humidity on May 29, 2013, uncovered for 60 minutes. Exposure began once the test substance was applied. Following, each carrier was removed from the larger carpet piece and transferred with carpet side down to individual vessels containing 100 mL of Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.25% Catalase neutralizing solution and 10 stainless steel penicylinders. Each vessel was shaken vigorously for at least 1 minute. For *Staphylococcus aureus*, ten-fold dilutions were prepared and 1.00 mL aliquots of the 10<sup>0</sup> through 10<sup>-3</sup> dilutions were plated in duplicate onto Tryptic Soy Agar + 5% Sheep Blood agar plate medium. For *Enterobacter aerogenes*, ten-fold dilutions were prepared and 1.00 mL aliquots of the 10<sup>0</sup> dilution and 0.100 mL aliquots of 10<sup>0</sup> through 10<sup>-2</sup> dilutions and plated in duplicate onto Tryptic Soy Agar + 5% Sheep Blood plate medium. All plates and controls were incubated for 48 ± 4 hours at 25 – 30°C for *Enterobacter aerogenes* and at 35 – 37°C for *Staphylococcus aureus* prior to visual examination for growth. Controls included suspension population control, population control, scrubbed population control, unscrubbed population control, sterility, purity, and neutralization confirmation.

**2. MRID # 492331-14. “Carpet Sanitizer,” Test Organism: *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538), for product Rug Doctor Antibacterial Carpet Sanitizer, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – October 16, 2013. Project Identification Number A15388.**

The study was conducted against *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538). One lot, Lot No. AB12-060713, of the product Rug Doctor Antibacterial Carpet Sanitizer were tested using ATS Labs protocol No. RUG01032713.CSAN (copy provided). The product was received as a ready to use trigger spray. A culture of the challenge microorganism was prepared by daily transfers of the organism on Nutrient A slants for ≥3 but ≤30 transfers. The final growth was washed from a 24 ± 2 hours Nutrient A slant using 5.0 mL of phosphate buffer dilution water (PBDW), aspirated, and added to 99.0 mL PBDW. A 2.0 mL aliquot of the inoculum suspension was then added to sufficient Nutrient Agar B bottles and incubated with agar side down for 18 – 24 hours at 25 – 30°C for *Enterobacter aerogenes* and 35 – 37°C for *Staphylococcus aureus*. Following incubation, a 3.0 mL aliquot of PBDW and approximately 15 – 20 sterile glass beads were added to each bottle to suspend the growth. The growth suspension was removed and filtered through sterile gauze pre-wetted with 1.0 mL of PBDW to ensure that any agar harvested with the organism was removed from the test suspension. A 0.20 mL aliquot of Fetal Bovine Serum was added to 3.80 mL of each broth culture to yield a 5% organic soil load. The carriers, sterilized square cut (2 inch X 2 inch) polyester and nylon carpet, were inoculated with 100 µL of the prepared test culture and spread over the upper surface of the carpet using a sterile loop. The inoculated carpet was dried in an incubator at 35 – 37°C with 52 – 54.7% relative humidity for 60 minutes with sterile foil loosely covering the carpet. Each carrier was sprayed with the test substance for 10 sprays at a distance

of 3 inches. Each carpet carrier was then scrubbed for 30 seconds using 30 circular counterclockwise strokes around a circular area of pile approximately 3 inches (7.6 cm) in diameter around the center of each carrier using a surgical hand brush (4 ¼ X 1 5/8 inch) with ½ inch bristles. For each carpet square, a new sterile brush was used. The treated and scrubbed carpet remained at 22°C with 52-59% relative humidity uncovered for 59 minutes. Exposure began once the test substance was applied. Following, each carrier was removed from the larger carpet piece and transferred with carpet side down to individual vessels containing 100 mL of Lethen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.25% Catalase neutralizing solution and 10 stainless steel penicylinders. Each vessel was shaken vigorously for at least 1 minute. For *Staphylococcus aureus*, ten-fold dilutions were prepared and 1.00 mL aliquots of the 10<sup>0</sup> through 10<sup>-3</sup> dilutions were plated in duplicate onto Tryptic Soy Agar + 5% Sheep Blood agar plate medium. For *Enterobacter aerogenes* testing performed on 8/9/13, ten-fold dilutions were prepared and 1.00 mL aliquots of the 10<sup>0</sup> dilution and 0.100 mL aliquots of 10<sup>0</sup> through 10<sup>-2</sup> dilutions and plated in duplicate onto Tryptic Soy Agar + 5% Sheep Blood plate medium. stainless steel penicylinders. Each vessel was shaken vigorously for at least 1 minute. For *Enterobacter aerogenes* testing performed on 8/27/13, ten-fold dilutions were prepared and 1.00 mL aliquots of the 10<sup>0</sup> and 0.100 mL aliquots of 10<sup>0</sup> through 10<sup>-3</sup> dilutions were plated in duplicate onto Tryptic Soy Agar + 5% Sheep Blood agar plate medium. All plates and controls were incubated for 48 ± 4 hours at 25 – 30°C for *Enterobacter aerogenes* and at 35 – 37°C for *Staphylococcus aureus* prior to visual examination for growth. Subcultures performed on 8/9/13, were stored at 2 – 8°C for 1 day prior to examination. Controls included suspension population control, population control, scrubbed population control, unscrubbed population control, sterility, purity, and neutralization confirmation.

Note: Testing against *Enterobacter aerogenes* using polyester carriers was repeated on August 27, 2013 due to invalid results for the carrier scrubbed population control for test date August 9, 2013.

**3. MRID # 492331-15. "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Modification for Spray Product Application," Test Organism: *Klebsiella pneumonia* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538), for product Rug Doctor Antibacterial Carpet Sanitizer, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – July 24, 2013. Project Identification Number A14807.**

The study was conducted against *Klebsiella pneumonia* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538). Three lots, Lot No. AB06-103112 (≥60 days old), Lot No. AB08-12714, and Lot No. AB11-030713/B, of the product Rug Doctor Antibacterial Carpet Sanitizer were tested using ATS Labs protocol No. RUG01012413.NSF.2 (copy provided). The product was received as a ready to use trigger spray. A culture of the challenge microorganism was prepared from the initial broth suspension by more than three but less than thirty daily consecutive transfers of one loopful (10 µL) of culture in 10 mL of the appropriate growth medium of Nutrient broth. The last culture transfer suspension was incubated 48 - 54 hours, vortex-mixed, and allowed to stand for ≥ 15 minutes prior to removing the upper 2/3rds portion of the culture and transferring it to a sterile vessel for use in testing. Fetal bovine serum was added to the culture to achieve a final 5% organic soil load. Scouring of the fabric carriers was performed before inoculation with test organisms.

For testing performed on April 4, 2013:

For the 100% polyester fabric for testing, a scouring solution was prepared by adding 2.8531 grams of  $\text{Na}_2\text{CO}_3$  and 2.8519 grams of Triton X-100 to 5.7 L of deionized water. For the polyester fabric for testing, a 568.88 gram sample of test fabric was added to 5.7 L of the prepared scouring solution. For the plain cotton weave fabric for testing, a scouring solution was prepared by adding 1.5 grams of  $\text{Na}_2\text{CO}_3$  and 1.5 grams of Triton X-100 to 3 L of deionized water. For plain cotton weave (80 x 80 threads/inch) fabric, 300 grams of test fabric sample was added to 3 L of prepared scouring solution.

For testing performed on May 17, 2013:

For the 100% polyester fabric for testing, a scouring solution was prepared by adding 2.1211 grams of  $\text{Na}_2\text{CO}_3$  and 2.1502 grams of Triton X-100 to 4.2 L of deionized water. For the polyester fabric for testing, a 417.78 gram sample of test fabric was added to 4.2 L of the prepared scouring solution. For the plain cotton weave fabric for testing, a scouring solution was prepared by adding 3.04 grams of  $\text{Na}_2\text{CO}_3$  and 3.02 grams of Triton X-100 to 6 L of deionized water. For plain cotton weave (80 x 80 threads/inch) fabric, 585.7 grams of test fabric sample was added to 6 L of prepared scouring solution.

The scouring solutions containing fabric (carriers) were allowed to boil for approximately 60 minutes followed by removal and subsequent rinsing in boiling water for a minimum of 5 minutes and then placing the fabric into cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in order to help remove the wetting agent. The fabric was allowed to air dry. The fabric carriers were cut to a size of approximately 1"x 1" and were autoclave sterilized. After sterilization, each carrier was placed into a sterile Petri dish prior to use in testing. Individual fabric carriers (1"x1") were inoculated with 30.0  $\mu\text{L}$  of test organism using a calibrated pipettor. The inoculated carriers were allowed to dry for 10 minutes at 35-37°C at 40% relative humidity. Following, for each lot of test substance, 5 test carriers each of cotton and polyester for each test organism were sprayed (using 2 sprays) in a horizontal position with the test substance at a distance of 3 inches from the carrier surface. For testing performed on April 4, 2013, the carriers were allowed to remain wet for 5 minutes at room temperature (22°C) at 21% relative humidity in Petri dishes. For testing performed on May 17, 2013, the carriers were allowed to remain wet for 5 minutes at room temperature (21°C) at 49% relative humidity in Petri dishes. Following the exposure period, the individual carriers were transferred to neutralizing solution containing Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.25% Catalase. Following neutralization, the excess liquid in each Petri dish was transferred to the neutralization jar containing the corresponding carrier and vortex with glass beads to aid in organism recovery. Within 30 minutes of neutralization, aliquots of the neutralization solution, including serial dilutions were plated onto recovery agar plate medium of Tryptic Soy Agar with 5% Sheep Blood. For *S. aureus* testing performed on April 4, 2013, duplicate 1.0 mL of neutralized solution and 1.0 mL aliquots of the ten-fold diluted neutralized solution was plated. For *K. pneumoniae* testing performed on April 4, 2013, duplicate 1.0 mL and 0.100 mL aliquots of a ten-fold serial dilutions were plated. For testing performed on May 17, 2013 for both organisms, duplicate 1.0 mL and 0.100 mL aliquots of the ten-fold serial dilutions were plated. For both testing dates, the *S. aureus* and *K. pneumoniae* were incubated at 35-37° for 48±4 hours. The subcultures from testing performed on April 4, 2013 were placed at 2-8°C for 3 days prior to examination. The subcultures from testing performed on May 17, 2013 were placed at 2-8°C for 2 days prior to examination. Plates and subcultures

were visually examined for the presence or absence of growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

## V. RESULTS:

### MRID # 492331-13 Carpet Sanitization: Test Date April 3, 2013

Organism	Lot No.	Carrier Type	Geometric mean of # Survivors/ Carrier (Log)	Geometric Mean Unscrubbed (Log) CFU/Carrier	Geometric Mean Scrubbed (Log) CFU/Carrier	Percent Reduction
			60 minutes contact time			
<i>Staphylococcus aureus</i>	AB06-103112	Nylon	<1.91 X 10 <sup>2</sup>	2.88 X 10 <sup>8</sup>	9.33 X 10 <sup>7</sup>	>99.9%
	AB08-122712		<1.00 X 10 <sup>2</sup>			>99.9%
	AB06-103112	Polyester	3.63 X 10 <sup>4</sup>	1.82 X 10 <sup>8</sup>	8.51 X 10 <sup>7</sup>	>99.9%
	AB08-122712		3.16 X 10 <sup>5</sup>			99.6%
	AB08-122712 Test Date May 29, 2013		3.24 X 10 <sup>3</sup>	8.91 X 10 <sup>7</sup>	1.12 X 10 <sup>8</sup>	>99.9%
<i>Enterobacter aerogenes</i>	AB06-103112	Nylon	<1.00 X 10 <sup>2</sup>	3.55 X 10 <sup>8</sup>	4.47 X 10 <sup>7</sup>	>99.9%
	AB08-122712		<1.00 X 10 <sup>2</sup>			>99.9%
	AB06-103112	Polyester	1.29 X 10 <sup>6</sup>	5.62 X 10 <sup>8</sup>	5.37 X 10 <sup>8</sup>	99.8%
	AB08-122712		8.32 X 10 <sup>5</sup>			99.8%
	AB06-103112 Test Date May 29, 2013		<1.00 X 10 <sup>2</sup>	2.63 X 10 <sup>8</sup>	8.32 X 10 <sup>7</sup>	>99.9%
	AB08-122712 Test Date May 29, 2013		<1.00 X 10 <sup>2</sup>			>99.9%

☐ Shaded box indicates repeat test date.

**MRID # 492331-14 Carpet Sanitizer: Test Date August 9, 2013**

Organism	Lot No.	Carrier Type	Geometric mean of # Survivors/ Carrier (Log)	Geometric Mean Unscrubbed (Log) CFU/Carrier	Geometric Mean Scrubbed (Log) CFU/Carrier	Percent Reduction
			60 minutes contact time			
<i>Staphylococcus aureus</i>	AB12-060713	Nylon	<1.00 X 10 <sup>2</sup>	1.12 X 10 <sup>8</sup>	7.76 X 10 <sup>7</sup>	>99.9%
	AB12-060713	Polyester	8.91 X 10 <sup>4</sup>	1.02 X 10 <sup>8</sup>	9.12 X 10 <sup>7</sup>	99.9%
<i>Enterobacter aerogenes</i>	AB12-060713	Nylon	<2.29 X 10 <sup>3</sup>	>3.02 X 10 <sup>8</sup>	2.09 X 10 <sup>8</sup>	>99.9%
	AB12-060713 Test Date: 8/27/13	Polyester	5.25 X 10 <sup>3</sup>	3.16 X 10 <sup>8</sup>	2.51 X 10 <sup>8</sup>	>99.9%

**MRID # 492331-15 Soft Surface Non-Food Contact Sanitizer: Test Date April 4, 2013**

Organism	Lot No.	Carrier Type	Geometric mean of # Survivors/ Carrier (Log)	Geometric Mean (Log) CFU/Carrier	Percent Reduction
			5 minutes contact time		
Staphylococcus aureus	AB06-103112	Plain Cotton Weave	$<2.29 \times 10^1$	$2.88 \times 10^7$	>99.9%
	AB08-122712		$<2.51 \times 10^1$		>99.9%
	AB11-030713/B Test Date May 17, 2013		$<3.63 \times 10^1$	$4.37 \times 10^7$ Test Date May 17, 2013	>99.9%
	AB06-103112	100% Polyester	$<2.00 \times 10^1$	$3.31 \times 10^7$	>99.9%
	AB08-122712		$<2.00 \times 10^1$		>99.9%
	AB11-030713/B Test Date May 17, 2013		$<2.29 \times 10^1$	$7.08 \times 10^7$ Test Date May 17, 2013	>99.9%
Klebsiella pneumoniae	AB06-103112	Plain Cotton Weave	$<2.00 \times 10^1$	$6.92 \times 10^7$	>99.9%
	AB08-122712		$<2.00 \times 10^1$		>99.9%
	AB11-030713/B Test Date May 17, 2013		$<2.00 \times 10^1$	$5.13 \times 10^7$ Test Date May 17, 2013	>99.9%
	AB06-103112	100% Polyester	$<2.00 \times 10^1$	$3.89 \times 10^7$	>99.9%
	AB08-122712		$<2.00 \times 10^1$		>99.9%
	AB11-030713/B Test Date May 17, 2013		$<2.00 \times 10^1$	$5.75 \times 10^7$ Test Date May 17, 2013	>99.9%

## VI. CONCLUSIONS:

1. The submitted efficacy data does support the use of the product, Rug Doctor Antibacterial Carpet Sanitizer, as a carpet sanitizer with bactericidal activity against the following microorganisms on nylon and polyester tufted-loop types of carpets in the presence of a 5% organic soil load for a 60 minutes contact time:

<i>Staphylococcus aureus</i>	MRID #492331-13 & MRID # 492331-14
<i>Enterobacter aerogenes</i>	MRID #492331-13 & MRID # 492331-14

A 99.9% reduction of the test bacteria over the scrubbed control count was demonstrated on two different representative synthetic carpeting. Neutralization confirmation testing showed positive growth of the microorganisms. Sterility controls did not demonstrate growth. Purity controls were pure.

2. The submitted efficacy data does support the use of the product, Rug Doctor Antibacterial Carpet Sanitizer, as a non-food contact soft surface sanitizer with bactericidal activity against the following microorganisms on plain cotton weave and 100% polyester fabrics in the presence of a 5% organic soil load for a 5 minutes contact time:

<i>Staphylococcus aureus</i>	MRID # 492331-15
<i>Klebsiella pneumoniae</i>	MRID # 492331-15

A 3 log reduction of the test bacteria was demonstrated on two different fabric types within 5 minutes. Neutralization confirmation testing showed positive growth of the microorganisms. Sterility controls did not demonstrate growth. Purity controls were pure.

## VII. RESULTS:

1. The proposed label claims the product, Rug Doctor Antibacterial Carpet Cleaner, is an effective carpet sanitizer on nylon and polyester tufted-loop types of carpets in the presence of a 5% organic soil load for a 60 minutes contact time:

<i>Staphylococcus aureus</i>	ATCC6538
<i>Enterobacter aerogenes</i>	ATCC 13048

These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims the product, Rug Doctor Antibacterial Carpet Cleaner, is an effective non-food contact soft surface sanitizer on plain cotton weave and 100% polyester fabrics in the presence of a 5% organic soil load for a 5 minutes contact time:

<i>Staphylococcus aureus</i>	ATCC 6538
<i>Klebsiella pneumoniae</i>	ATCC 4352

These claims are **acceptable** as they are supported by the submitted data.

## **LABEL RECOMMENDATIONS:**

- Page 1, remove “[Deep (Spot) Clean(er) + Sanitizer]. It is false is misleading. The approved sanitization claims are for use on the surface of the use sites.
- Throughout the Sanitizing claims, remove the word “Deep”. It is false is misleading. The approved sanitization claims are for use on the surface of the use sites.
- Page 4 and 5, in the directions for use, the statement “Hold the spray bottle approximately 3 inches from surface of the carpeting and spray a light even coating on soiled are (until damp).” must be rewritten to state “Hold the spray bottle approximately 3 inches from surface of the carpeting and spray a even coating on soiled are until damp”. The instructions must include directions as performed in the approved testing.
- Throughout the Sanitizing claims, each claim for bacteria must be qualified. It is misleading without qualification by implying that the product sanitizes all bacteria.
- Page 9, remove the statement “Neutralizes and reduces the growth of bacteria”. This is misleading as it implies bacteriostatic properties.
- Page 9 & 10, rewrite the statement “Sanitizes as it cleans” to state “Cleans as it sanitizes”. Sanitization requires a contact time whereas cleaning does not. Therefore, cleaning will not promote sanitization without allowing the contact time period.
- Page 10, remove the statements “Penetrated (deep down) to (thoroughly) clean and sanitize”, “Penetrates (deep down) to thoroughly remove (stains) (bacteria\*), (and) (odors)”, and “Go beyond surface cleaning- unique penetrating action thoroughly cleans and sanitizes deep into the carpet fibers”. These statements are false and misleading. The approved sanitization claims are for use on the surface of the use sites.
- Page 11, remove the word sanitize within the statements or the entire statements “Unique penetrating action goes deep within carpet fibers to thoroughly clean and sanitize-eliminating dirt, stains, odors, bacteria, and allergens” and “Penetrates to sanitize(s) and (clean) (loosen(s)) (tough) stains (including (spaghetti sauce) (coffee) (mud) (wine) (pet stains) (cola) (tea) (food grease)”. These statements are false and misleading. The approved sanitization claims are for use on the surface of the use sites.
- Page 11, remove the statement “Cleans and sanitizes (blood) (sweat) (drool) (insect droppings) (feces) (fecal matter) (food stains) (&) (vomit)”. These statements are false and misleading. The approved sanitization claims are for use on the surface of the use sites. Data submitted does not support penetrating sanitizing claims.
- Page 11, the terms “Antimicrobial” and “Antibacterial” must be qualified. It is misleading without qualification by implying that the product sanitizes all microbes and bacteria.
- Page 12, remove all statements that include a reference to EPA. This implies endorsement by the Agency.
- Page 12, remove the statement “Environmentally friendly”. This is false and misleading. Data was not submitted that supports this claim.